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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/577,132	08/28/2006	Patrice Richard	Q94512	8183

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EXAMINER	
SU, SUSAN SHAN	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
10/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/577,132	RICHARD, PATRICE	
	Examiner	Art Unit	
	SUSAN SU	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,3-10,12,13,15,17 and 20* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,3-10,12,13,15,17,20* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Reopening of Prosecution After Appeal

1. In view of the Reply Brief filed on 4/4/11, PROSECUTION IS HEREBY REOPENED. New grounds of rejection are set forth below.

To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111 (if this Office action is non-final) or a reply under 37 CFR 1.113 (if this Office action is final); or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Tatyana Zalukaeva/

Supervisory Patent Examiner, Art Unit 3761.

Status of Claims

Claims 1, 3-10, 12, 13, 15, 17, and 20 are pending, of which claims 1, 3, 5, 6, 9, 13, 15, and 17 are amended and claim 20 is new. Claims 2 & 19 have been canceled by this amendment filed on 7/7/11. No new matter is added.

Response to Arguments

2. Applicant's arguments filed 4/4/11, with respect to the new grounds of rejection presented in the Examiner's Answer of 2/3/11, have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, since new amendments to the claims are filed after the Examiner's Answer, a new ground(s) of rejection is made in view of Stone.

Claim Interpretation under 35 USC § 112, 6th paragraph

3. Claim limitation "means for sucking and collecting placental-blood" has been interpreted under 35 U.S.C. 112, sixth paragraph, because it uses a non-structural term "means" coupled with functional language "for sucking and collecting placental-blood" without reciting sufficient structure to achieve the function. Furthermore, the non-structural term is not preceded by a structural modifier.

Since this claim limitation invokes 35 U.S.C. 112, sixth paragraph, claim 13 is interpreted to cover the corresponding structure described in the specification that achieves the claimed function, and equivalents thereof.

A review of the specification shows that the following appears to be the corresponding structure described in the specification for the 35 U.S.C. 112, sixth

paragraph limitation: vacuum bottle, as disclosed on page 1 line 37 of the original Specification as filed.

If applicant wishes to provide further explanation or dispute the examiner's interpretation of the corresponding structure, applicant must identify the corresponding structure with reference to the specification by page and line number, and to the drawing, if any, by reference characters in response to this Office action.

If applicant does **not** wish to have the claim limitation treated under 35 U.S.C. 112, sixth paragraph, applicant may amend the claim so that it will clearly not invoke 35 U.S.C. 112, sixth paragraph, or present a sufficient showing that the claim recites sufficient structure, material, or acts for performing the claimed function to preclude application of 35 U.S.C. 112, sixth paragraph.

For more information, see *Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. § 112 and for Treatment of Related Issues in Patent Applications*, 76 FR 7162, 7167 (Feb. 9, 2011).

4. In the instant case, Examiner considers a syringe to be an equivalent to the "means for sucking and collecting placental-blood" disclosed by applicant, since it performs the same function (i.e. generating suction and also acts as a receptacle for the blood) in the same way, with the same result (i.e. suctioning and receiving the blood) as the device disclosed by Applicant. The equivalence between a syringe and a vacuum bottle is also supported by Grossman (US 2004/0116902) in [0004]. See MPEP 2183.

Claim Objections

5. Claim 15 is objected to because of the following informalities: inconsistency in claim terms. The recitation "sucking and collecting means" should be changed to -----means for sucking and collecting placental-blood-----. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claim 13 is rejected under 35 U.S.C. 102(b) as being anticipated by Stone (US 5,059,168). Stone teaches a placental-blood extraction device comprising:

an extraction needle (13) for piercing the vein of an umbilical cord or of a placenta,

a tube (inlet 17 of coupler 14 reads on "tube") in fluid connection with the needle; and

a means for sucking and collecting placental-blood, in fluid connection with the needle via the tube.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1, 3-7, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone in view of Grossman et al. (US 2004/0116902, "Grossman").

Re Claim 1, Stone teaches a placental-blood extraction device, comprising:

at least one extraction needle (13) for piercing the vein of an umbilical cord or of a placenta;

at least one tube (the inlet portion 17 can be considered a tube); and

a vacuum container (syringe 22) in fluid connection with said at least one needle via said at least one tube, for sucking and collecting placental blood directly therein,

wherein the vacuum container is the vacuum source for the placental-blood extraction device (since blood is aspirated into the syringe).

Stone does not explicitly teach that the vacuum container is a vacuum bottle. Grossman teaches a medical vacuum bottle (10) for suctioning bodily fluids wherein the vacuum bottle is the vacuum source. Grossman also explicitly discloses that syringes and vacuum bottles are equivalents in the medical field since both generate suction ([0004]). A substitution of a known equivalent used for the same purpose would be obvious to one skilled in the art (MPEP 2144.06). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone with the teachings of Grossman for the benefit of generating suction without constant effort (e.g. pulling the plunger of the syringe to generate suction) from the user.

Re Claim 3, Stone also teaches that the device includes at least one injection or extraction site (e.g. through outlet 18) between said at least one extraction needle and said vacuum bottle.

Re Claim 4, Stone also teaches that the at least one injection or extraction site is provided on the tube.

Re Claim 5, Stone does not teach that the at least one injection or extraction site is provided on the vacuum bottle. Grossman teaches providing an extraction site (through frangible seal 32, see Fig. 4 and [0039]) on the vacuum bottle such that the contents inside the bottle may be emptied ([0039]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone by the teachings of

Grossman for the benefit of providing an easy access to the contents of the vacuum bottle.

Re Claim 6, the language is functional. While features of an apparatus may be recited either structurally or functionally, claims directed to a device must be distinguished from the prior art in terms of structure rather than function, because device claims cover what a device is, not what a device does *(Hewlett-Packard Co. v. Bausch & Lomb Inc.,* 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990)). Thus, if a prior art structure is capable of performing the intended use as recited in the preamble, or elsewhere in a claim, then it meets the claim. The extraction site of Stone is capable of being used for extracting a sample of blood (Col. 2 lines 5-12), regardless of whether the blood is later used for analysis or transfusion.

Re Claim 7, Stone also teaches a blood-flow control means (stopcock 16) or suction control means.

Re Claim 17, Stone teaches a method of extracting fluid from an umbilical cord or a placenta comprising:

providing an extraction device (13) comprising an extraction needle, a vacuum container (syringe 22) in fluid connection with the needle via a tube (inlet 17), wherein the vacuum container is a vacuum source for the extraction device;

piercing the vein (inherent from the figure) of an umbilical cord (11) or of a placenta;

drawing out fluid from the vein using the vacuum created by the vacuum container (Col. 2 lines 20-24); and

collecting the fluid directly in the vacuum container.

Stone does not explicitly teach that the vacuum container is a vacuum bottle. Grossman teaches that syringes and vacuum bottles are known alternatives of vacuum sources in the medical field ([0004]). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone with Grossman for the benefit of providing suction and collection without constant action (e.g. pulling the plunger of the syringe to generate suction) from a practitioner.

11. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone and Grossman as applied to claim 7 above, and further in view of Darling, Jr. (US 6,213,986, "Darling"). Stone and Grossman do not explicitly teach that the blood-flow control means includes a knurled adjustment wheel. Darling teaches a medical device with a fluid-flow control means (10, Fig. 1) that includes a knurled adjustment wheel (110, Figs. 2-3). Furthermore, knurled adjustment wheels are commonly used in everyday life for fluid control, such as faucet knobs. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone and Grossman with Darling for the benefit of having a way to control the amount of flow with an easy-to-grip means.

12. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone and Grossman as applied to claim 1 above, and further in view of Dracker (US 5,356,373). Stone and Grossman do not explicitly teach an anti-coagulant inside the

vacuum bottle. Dracker teaches an apparatus for collecting umbilical cord blood wherein the blood receptacle contains anti-coagulant before receiving the blood (Col. 7 lines 23-32) such that blood would not coagulate inside the container. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone and Grossman with Dracker's teaching for the benefit of keeping blood fluidic and usable.

13. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone and Grossman as applied to claim 1 above, and further in view of Van Der Heiden et al. (US 5,879,318, "Van Der Heiden"). Stone and Grossman do not expressly teach that the device is packaged in sterile manner and is assembled in a single package so as to be ready to use once said package has been opened. Van Der Heiden teaches packaging a cord blood collection device in a sterile manner (Col. 6 lines 15-17) and is assembled in a single package that is ready to use (suggested by Col. 6 lines 35-36 because sterility for the entire closed system can be kept only if the system is already closed before the sterilization process and kept sterilized as a single connected system). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone and Grossman with Van Der Heiden for the purpose of preventing contamination of the device and subsequently the contents inside the device.

14. Claims 12 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stone and Grossman as applied to claim 1 or 17 above, and further in view of Seddon et al. (US 6,024,731, "Seddon"). Stone and Grossman do not explicitly teach that the vacuum bottle is of Redon type (through searching literature, e.g. US

5,078,704, “Redon type” bottle is understood to be a rigid bottle pre-charged with vacuum and provided with a pressure indicator and a wound exudate inlet). Seddon teaches a Redon type collection vessel (Col. 5 lines 1-3) used in a medical setting that creates a vacuum in fluid connection with a tube (see Fig. 1). Since the Redon bottle is a type of vacuum bottle that performs the same function as the vacuum bottle in the combination, it is a suitable selection for the intended purpose of acting as a vacuum source and receiving bodily fluids (see MPEP 2144.07). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone and Grossman with the Redon bottle of Seddon for the purpose of allowing the practitioner to gauge how much suction is left in the bottle.

15. Claim 15 is rejected under 35 U.S.C. 103(a) as being unpatentable over Stone in view of Grossman and Seddon. Stone also teaches that the means for sucking and collecting placental-blood (syringe 22) creates a vacuum source for the placental-blood extraction device and collects the placental-blood therein but does not teach that it includes a Redon vacuum bottle. Grossman teaches that a syringe and a vacuum bottle are both known vacuum sources in the medical field ([0004]), thus recognizing them as alternatives. Seddon teaches a Redon vacuum bottle (Col. 5 lines 1-3), which is simply one type of vacuum bottle that is provided with a pressure indicator. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Stone with the teachings of Grossman and Seddon for the benefit of utilizing a known alternative to achieve the same purpose (e.g. provide suction and receive body fluids) that does not require constant action from the practitioner (e.g. pulling on the plunger to

provide suction in the syringe) and to have a gauge of how much suction is left in the bottle.

Conclusion

16. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Lobodzinski teaches a medical system wherein the suction source can be a syringe, a vacuum bottle, or a drain bag.

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN SU whose telephone number is (571)270-3848. The examiner can normally be reached on M-F 10:00AM-6:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Su/
Examiner, Art Unit 3761
22 September 2011

/Tatyana Zalukaeva/
Supervisory Patent Examiner, Art Unit 3761